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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,179	08/08/2001	Paula M. Jardicu	P0718P2C1D1C1	5112

9157 7590 09/23/2003

GENENTECH, INC.
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EXAMINER

BLANCHARD, DAVID J

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 09/23/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/925,179

Applicant(s)

JARDIEU ET AL.

Examiner

David J Blanchard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58-78 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 58-78 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. It is acknowledged that applicants have responded to the election of species requirement in paper number 5 mailed herein on 6/30/2003. It is noted that applicants have elected 1) an IgG1 antibody 2) Asparagine at residue 60 and 3) Proline at residue 61 in paper number 6 mailed herein on 7/18/2003, however, the election of species requirement is vacated and all species will be examined.
2. Claims 58-78 are pending and are under examination.

Specification

3. The amendment filed in paper number 3 on 8/8/2001 requested the replacement of the original specification and drawings with the revised specification and formal drawings. However, it is noted that there appears to be no substitute specification or formal drawings. Additionally, there was no marked up copy of the specification supplied with the substitute specification showing the changes made by amendment. The examiner apologizes and it is requested that applicant resubmit the substitute specification, drawings and marked up copy to show the changes made from the original specification.

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4. It is acknowledged that the changes to the specification on page 30 and other places with regard to residues 29a, 29c and 30 being replaced by 30, 30b and 30d, respectively, are explained in the amendment filed on 8/8/2001 and support for this numbering is provided.

5. The disclosure is objected to because of the following informalities: It is requested that applicant update the priority information on page 1, line 7 of the disclosure with the patent number for U.S. Ser. No. 08/466,163 filed on June 6, 1995. The patent number is 6,329,509 B1.

6. It appears that the Tables have been misnumbered. There is a Table 5 on page 26 and a different Table 5 on page 38. Applicant is requested to renumber the Tables in sequence and applicant is reminded to check the entire disclosure and make the corresponding changes to reflect the renumbering of the Tables.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 58-62, 64-67, 69-72 and 74-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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a) Claims 58-60, 62, 64, 65, 67, 69, 70, 72, 74, 75 and 77 are indefinite for reciting "modified" in claims 58, 60, 62, 65, 67, 70, 72, 75 and 77. It is unclear whether "modified" means a single amino acid substitution, amino acid analog substitutions, insertions at a given amino acid position or adjacent to an amino acid position, deletions at a given amino acid position or adjacent to an amino acid position, chemical modifications, or are the residues linked to another protein, a toxin or radioactive label for therapeutic benefit, for examples. Further, are the residues "modified" in that they serve as acceptor or donor residues?

b) Claims 61, 66, 71 and 76 are indefinite for reciting "residues". It is unclear whether the phrase means that a single amino acid substitution is contemplated, or any two, or any three, or any four, or all of the amino acids are to be substituted in any order.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 58-78 are rejected under 35 U.S.C. as failing to comply with the written description requirement. The claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art

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that the inventor, at the time the application was filed, had possession of the claimed invention.

Claims 58-78 recite a humanized anti-IgE antibody with at least one specific heavy and light chain Kabat residue modified wherein the humanized anti-IgE antibody is an IgG1 or IgG2 or IgG3 or IgG4.

Generic claim 58 and dependent claims 61, 66, 71, and 76 recite that heavy chain Kabat residue 60 is "substituted with an amino acid residues selected from the group consisting of asparagine, glutamine, histidine, lysine and arginine". SEQ ID No. 8 (Figure 3) in the specification shows that there is a "Y" residue at position 60 and not an "A" residue as shown in Table 9, which shows a A60N (alanine to asparagine mutation at residue 60) mutation for mutants 7, 8, and 9. Likewise, generic claim 58 and dependent claims 63, 68, 73, and 78 recite that heavy chain Kabat residue 61 is substituted with an amino acid residue selected from the group consisting of proline, glycine, alanine, valine, leucine and isoleucine. SEQ ID No. 8 (Figure 3) shows an "A" residue at position 61 and not an asparagine residue as shown in Table 9, which shows a D61P (asparagine to proline mutation at residue 61) mutation for mutants 7 and 8. Therefore, Table 9 does not indicate the correct numbering according to SEQ ID NO: 8 and it is unclear whether the numbering disclosed in Table 9 uses the same numbering system as that used in SEQ ID No. 8 (Figure 3).

Furthermore, it is unclear where support for the mutation Y60N recited in claims 61, 66, 71, and 76 is found since residue 60 of SEQ ID No. 8 as shown in Figure 3 has a "Y" residue at position 60. Similarly, it is unclear where support for the mutation A61P

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recited in claims 63, 68, 73 and 78 is found since residue 61 of SEQ ID No. 8 as shown in Figure 3 has an "A" residue at position 61. Applicants are required to specifically point to where in the specification as originally filed support for the limitations are found or remove them from the claims.

Conclusion

11. No claim is allowed. Claims 58-78 are free of the prior art because the prior art does not teach or fairly suggest a humanized anti-IgE antibody having a variable heavy chain sequence of SEQ ID NO: 8 or a variable light chain sequence of SEQ ID NO: 9 wherein specific amino acid residues of the humanized anti-IgE antibody are substituted.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Blanchard, whose telephone number is (703) 605-1200. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in

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Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,
David Blanchard.
703-605-1200

A handwritten signature in black ink, appearing to read 'L. Helms', with a stylized, cursive flourish at the end.

LARRY R. HELMS, PH.D
PRIMARY EXAMINER